| Notice of Allowability | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/771,985 | HARPER ET AL. | |
| | Examiner | Art Unit | |
| | Taylor Victor Oh | 1625 | |

***-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--***

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *8/2/05*.

2. ☒ The allowed claim(s) is/are *1-2, and 4-13, renumbered as claims 1-12*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   **Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *10/14/05* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

The previous final rejection has been vacated.

The Status of Claims

Claims 1-2, and 4-13 are pending.

Claims 1-2, and 4-13 have been allowable.

Claim 3 is canceled.

Examiner's Amendment and Reasons of Allowance

I. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with an attorney of record, MR. A. David Joran on 10/14/05.

II. The application has been amended as follows:

In claim 1 on page 2 (amendment filed on 2/22/05):

The phrase " --, and wherein the excipients are selected from the group consisting of ethanol, glycerin, polyethylene glycol and propylene glycols, and wherein the concentrate comprises sertraline in an amount of about 1 to about 88 mg/ml--" after the term " liquid " has been added.

Claim 3 has been canceled.

In claim 7 , on page 2 (amendment filed on 2/22/05):

The phrase " -- claim 7 --" after the term " of " is replaced with the phrase " claim 6".

In claim 11 , on page 2 (amendment filed on 2/22/05):

The phrase " --, said concentrate comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients, wherein at least one of the excipients is liquid, and wherein the excipients are selected from the group consisting of ethanol, glycerin, polyethylene glycol and propylene glycols, and wherein the concentrate comprises sertraline in an amount of about 1 to about 88 mg/ml--" after the phrase " oral administration " has been added.

III. The following is an examiner's statement of reasons for allowance:

- The close references for the current invention are Doogan et al (U.S. 4,962,128) and Howard et al (U.S. 5,597,826) .
- The rejection of Claims 1-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 13 of U.S. Patent No. 6,727,283 has been withdrawn due to the Terminal Disclaimer filed on 9/15/04.

Doogan et al discloses an aqueous pharmaceutical composition containing sertraline hydrochloride for treating anxiety-related disorders ; in addition, oral pharmaceutical formulations can be flavored by means of various agents ; the composition contains sertraline or its pharmaceutically acceptable salt, flavoring agents.

Howard et al discloses an aqueous pharmaceutical composition containing sertraline hydrochloride with suspending agents, and preservatives ; in addition, oral pharmaceutical formulations can be flavored by means of various agents . Also, the reference indicates that pharmacologically acceptable anions include methanesulfonate .

However, the instant invention differs from the prior art in that the non-aqueous oral pharmaceutical composition contains 1 mg/ml to 88 mg/ml of sertraline with non-aqueous excipients such as ethanol , glycerin, the flavoring agent is menthol, the preservative is

butylhydroxytoluene. There is no motivation in the prior art to arrive at the current invention for producing the non-aqueous pharmaceutical composition containing sertraline. In addition, unless all limitations of the claims are met, there is no prior art rejection. See In re Zurko 59 USPQ 2d 1690 (Fed Cir. 1991) and In re Lee, 61 USPQ 1430 (Fed Cir. 1991).

Therefore, applicants' claimed subject matter would not have been obvious to the person with an ordinary skill in the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

10/14/05

Cecilia J. Tsang
Supervisory Patent Examiner
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